

## **REMARKS**

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-8 and 18-24 are pending in this application. New claims 21-24 present alternative embodiments of the claimed invention. The upper range of 20°C in new claim 21 is within the original ranges in the specification and is further supported by the declaration from Dr. Ford previously presented. Support for the upper range of 20°C in new claim 21 can be found e.g. in Example 7 of the specification. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112.

### **II. THE 35 U.S.C. 112, 1<sup>st</sup> PARAGRAPH REJECTION HAS BEEN OVERCOME**

Claims 1-8 and 18-20 were rejected as allegedly lacking enablement for the full scope of the claimed invention. In order to expedite prosecution, the applicants have deleted the reference to solvates of the isocyanate of formula V. The applicants reserve the right to pursue the scope of original claim 1 in a continuation application.

### **III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME**

**A.** Claims 1-8 and 18-20 were rejected as allegedly being obvious over Vermehren et al. (DE 199 463 41 (U.S. Patent 7,026,477) - “Vermehren”) in view of Stubbs et al. (American Medical Journal, 50, pp. 193-204, 1913 - “Stubbs”) and Chiang et al. (EP 759 431 – “Chiang”).

**B.** Claims 1-8 and 18-20 were rejected as allegedly being obvious over Vermehren et al. (DE 199 463 41 (U.S. Patent 7,026,477) - “Vermehren”) in view of Koike et al. (US 4,211,723 - “Koike”) and Chiang et al. (EP 759 431 – “Chiang”).

As these rejections are essentially duplicative in nature, they are addressed collectively below.

For comparative purposes, the applicants have prepared the following charts which summarize the various steps of the claimed and prior art processes (see next page):

Claim 1 steps		step (a')		step (a)		step (b)				step (c)	
Claim 1	Formula (IIb)	→	Formula (IIa)	→	Formula (III)	→			Formula (V)	(IV) →	Formula (I)
Vermehren	n/A	n/A	n/A	n/A	(II)	ammonolysis →	(III)	phosgene →	(IV)	(V) →	(I)
Stubbs Koike	n/A	n/A	(IIa)	→	(III)	n/A			n/A	n/A	n/A
Chiang	n/A	n/A	n/A	n/A	(II)	→			(V)	(VI) →	(I)

- Shaded area indicates that the step is not available (n/A) or is different than in claim 1
- For Vermehren's process steps, the compounds used are similar to those used in claim 1; Vermehren's labeling is used in this row for easier correlation to Vermehren's specification
- For Chiang's process steps, the compounds used are similar to those used in claim 1; Chiang's labeling is used in this row for easier correlation to Chiang's specification

### Step (a') not taught

Both rejections acknowledge that Vermehren differs in not teaching the step (a') of the instant process which require the conversion of the free acid compound of Formula (IIb) to the compound of Formula (IIa). This difference is not addressed by the combination of Vermehren, Stubbs/Koike and Chiang.

### Step (b) for claim 1 as amended is not taught

Vermehren also differs from the applicants' claimed process in that it does not teach step (a) of the presently claimed process. The Stubbs and Koike references are presented to address this deficiency of the Vermehren reference.

Vermehren also differs from the applicants' claimed process by not referring to original step (b2) of claim 1 (now step (b) in the claims as amended) describes forming the compound of formula (V) by converting the compound of formula (III) with a cyanate. The Chiang reference is relied upon for addressing this difference.

While there are some surface similarities between Chiang and Vermehren, Chiang would not direct one of ordinary skill in the art to the applicants' claimed process of making sulfonylureas.

In addition to having the "wrong" substitution pattern on the phenyl ring for the final product (1,2,3 substitution in Chiang vs. 1,2,4 substitution in the present claims), the combination of Vehrmehren, Stubbs/Koike and Chiang do not teach or suggest the unexpectedly superior properties associated with steps (b) and (c) as claimed when used in combination.

Example 7 from the specification shows that when step (b) was performed at a temperature range of 6-10°C and step (c) at 40°C for step (c), the resulting product from applicants' process was the desired *sulfonylurea and NOT sulfonamide* when the Dr. Ford replicated Chiang's process step at room temperature (25°C) within the preferred temperature ranges described by Chiang for steps (b) and (c) is 15°C to 35°C. Not only were the applicants unexpectedly able to obtain the desired sulfonylurea, but also did so with excellent yield (77.3%) and purity (98% by HPLC).

The declaration previously submitted by Dr. Ford (signed on 15 April 2010) is also evidence of unexpected results. The Office Action looked at the individual process steps in isolation, but did not consider the invention or the cited references as a whole, i.e. the effect when the claimed process steps are used in combination. As noted above, the declaration by Dr. Ford showed that when following conditions suggested by Chiang, one of ordinary skill in the art obtains sulfonamide compounds and not sulfonylureas. In contrast, the reaction conditions practiced by Dr. Ford which are within the temperature ranges presently claimed (step (b) - 20°C; step (c) – 55-60°C), surprisingly did result in sulfonylureas (and with excellent yield (78%).

For these reasons, the applicants' claimed process for making sulfonylureas is unobvious over the combination of Vermehren, Stubbs/Koike and Chiang.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
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